REMARKS

Claims 1-5, 7-9, 11-19, 21-27, 29, 31, 33-35, 37, 40, 42-43, 47, 50, 52, 55, 57, 59, 61-65, 68, 70, 72, and 74-77 are pending in the instant application. Claims 11-19, 23-27, 29, 31, 33-35, 37, 40, 42-43, 47, 50, 52, 55, 57, 59, 61-65, 68, 70, 72, and 74-77 have been withdrawn from consideration. Claims 11-19, 21-27, 29, 31, 33-35, 37, 40, 42-43, 47, 50, 52, 55, 57, 59, 61-65, 68, 70, 72, and 74-77 have been canceled. Claims 1, 3-5, 7-9, 21 and 22 have been rejected. Claim 2 has been objected to for being dependent from a rejected base claim. Claims 1, 3-5, 7, and 8 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction Requirement Under 35 U.S.C. §121

The restriction requirement placing the claims into Groups I-XVIII has been deemed proper and made final. The Examiner suggests that the search of sense and antisense sequences of SEQ ID NO:1 would not be coextensive because the inventions are classified differently, necessitating different searches which would pose a serious burden on the Examiner. Thus, claims 11-19, 23-27, 29, 31, 33-35, 37, 40, 42-43, 47, 50, 52, 55, 57, 59, 61-65, 68, 70, 72, and 74-77 have been withdrawn from further consideration. Accordingly, Applicant is canceling claims 11-19, 23-27, 29, 31, 33-35, 37, 40, 42-43, 47, 50, 52, 55, 57, 59, 61-65, 68, 70, 72, and 74-77 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Rejection of Claims Under 35 U.S.C. §101

Claims 5 and 7 have been rejected under 35 U.S.C. §101 because they do not distinguish over host cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the products and the naturally occurring products. The Examiner suggests amending the claims to read on "isolated" or "purified" host cells as taught by page 50 of the specification. Applicant has amended claims 5 and 7 as suggested. Withdrawal of this rejection is therefore respectfully requested.

III. Rejection of Claims Under 35 U.S.C. §112

Claims 21 and 22 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the phrase "biologically effective amount" is not defined in the claim, and the specification does not provide a standard for ascertaining the requisite degree. Further, the term "substantially" in claim 22 has been suggested as rendering the claim indefinite.

Applicant has canceled claims 21 and 22, therefore withdrawal of this rejection is respectfully requested.

Claims 3-5, 7-9 and 21 have also been rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for reciting the term HGFIN in association with encoding characteristics as the sole means of identifying the claimed molecule. The Examiner suggests that this rejection can be

obviated by amending the claims to specifically and uniquely identify HGFIN, *e.g.*, by SEQ ID NO. and function of HGFIN.

Accordingly, Applicant has amended claims 3-5 and 7-9 to more accurately define the polynucleotide of the present invention. The inventive polynucleotide is defined as encoding a polypeptide having the function of a Hematopoietic Growth Factor Inducible Neurokinin-I type polypeptide and having a high degree of identity to SEQ ID NO:1 (*i.e.*, at least 97% identity). Support for this amendment can be found at paragraphs [0027] and [00103]. In view of this amendment, it is respectfully requested that this rejection be withdrawn.

Claims 1, 3-5, 7-9 and 21-22 have also been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the claims are inclusive of a genus of polynucleotides that have at least 70% identity to SEQ ID NO:1 or to a genus of molecules referred to as "HGFIN"; however, the written description only sets forth an HGFIN nucleotide sequence of SEQ ID NO:1 that encodes the amino acid sequence of SEQ ID NO:2. The Examiner suggests that the instant specification fails to provide sufficient structural or function features that are common to the genus of HGFIN polynucleotides or HGFIN polypeptides. It is suggested that because the specification fails to describe the common attributes or characteristics that identify the members of the genus, and the genus is highly variant, the disclosure of one species of HGFIN polynucleotides and polypeptides is insufficient to describe the genus. Applicant respectfully traverses this rejection.

MPEP 2163.02 indicates that an objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

Applicant teaches an HGFIN polynucleotide of SEQ ID NO:1 which was identified by hybridization with an NK-1-specific probe having a sequence available under Accession No. M74290 (Created 03-AUG-1993). The HGFIN polynucleotide encodes a protein which is 97% homologous to NMB precursor protein (SwissProt Q14956)(See paragraphs [00101] at page 34 and [00109] at page 42) and has a PKD region which is homologous to the PMEL-17 class of proteins found in polycystic kidney disorder, available to one of skill in the art in the RCSB protein database (see paragraph [00109] at page 42). At the time of filing, the coding sequences for NMB was also readily available to the skilled artisan under Accession No. X76534 (Submitted 03-DEC-1993).

The claims have been amended to recite a Hematopoietic Growth Factor Inducible Neurokinin-I type polynucleotide having at least 97% identity with SEQ ID NO:1. The specification teaches that HGFIN polynucleotides sharing a high degree of identity with SEQ ID NO:1 can be identified by using hybridization and washing

conditions of appropriate stringency as disclosed in paragraphs [0105]-[0107] and computer-based sequence comparisons (see paragraph [0066]. The specification further teaches HGFIN polypeptides of SEQ ID NO:2 may be identical to the polypeptide encoding sequence contained in SEQ ID NO:1, or it may be a sequence, which as a result of the redundancy (degeneracy) of the genetic code, also encodes the polypeptide of SEQ ID NO:2 (see paragraph [0105]). In addition to redundancy at the wobble position, changes to the nucleotide sequence are taught which preferably produce protein variants with conservative amino acid substitutions such that the resulting protein has the same structure, stability characteristics, substrate specificity and/or biological activity of the HGFIN polypeptide of SEQ ID NO:2. See paragraph [0117] in view of paragraphs [0063] and [0064].

Thus, in view of the prior art, Applicant has provided an adequate description of the structure of HGFIN polynucleotides (*i.e.*, sharing at least 97% identity with SEQ ID NO:1), suitable changes to the polynucleotide which provide a polynucleotide that falls within the scope of the present invention (*i.e.*, redundant changes at the wobble position and changes to the nucleotide sequence which produce protein variants with conservative amino acid substitutions), the conditions under which these polynucleotides are expressed (*i.e.*, in the presence of Hematopoietic Growth Factor), how to identify HGFIN polynucleotides which fall within the scope of the claimed invention (*i.e.*, hybridization and washing conditions, and computer-based sequence comparisons), and structural and functional characteristics of the encoded HGFIN proteins (*i.e.*,

structure of SEQ ID NO:2, homology to NK-1 and NMB, Neurokinin-I type receptor having a PKD region, and variants with conservative substitutions which preserve the structure, stability characteristics, substrate specificity and/or biological activity of the HGFIN polypeptide of SEQ ID NO:2). Accordingly, one of skill in the art would readily recognize that a polynucleotide containing a subset of the substitutions present in the NMB polynucleotide sequence of Accession No. X76534, wherein the subset of substitutions resulted in a polynucleotide having at least 97% identity with SEQ ID NO:1, would be considered a polynucleotide encoding an HGFIN polypeptide. Therefore, the written description requirement has been met. Withdrawal of this rejection is requested.

Claims 21 and 22 have further been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner suggests that because the instant claims read on a pharmaceutical composition comprising a biologically effective amount of a HGFIN polynucleotide and an acceptable carrier, that the claims imply a method of using the pharmaceutical composition for treating a disease. It is further suggested that the specification fails to teach an appropriate dose for humans, the amount of HGFIN gene expression necessary for successful treatment, the number of cells to be treated, the number of times the treatment needs to be administered, the appropriate route of administration, or the *in vivo* efficacy of the HGFIN polynucleotide.

In view of Applicant's cancellation of claims 21 and 22, withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims Under 35 U.S.C. §102

Claims 1, 3-5 and 7-8 have been rejected under 35 U.S.C. 102(b) as being anticipated by Weterman et al. ((1995) *Int. J. Cancer* 60:73-81). The Examiner suggests that Weterman et al. teach the isolation and characterization of a nucleic acid referred to as NMB which appears to have 95.7% identity to SEQ ID NO:1 of the present invention. It is further suggested that Weterman et al. teach transfection of NMB into a highly metastatic cell line, wherein the cells were transfected with an expression vector containing NMB cDNA, and that the protein encoded by NMB appears to be identical to the polypeptide (SEQ ID NO:2) encoded by SEQ ID NO:1. Applicant respectfully disagrees.

Weterman et al. teach a polynucleotide that appears to share 95.7% identity with SEQ ID NO:1. As claim 1, and claims dependent therefrom, has been amended to read on a polynucleotide that shares at least 97% identity with SEQ ID NO:1, the polynucleotide of Weterman et al. does not fall within the scope of the claimed polynucleotide and therefore does not anticipate it. It is therefore respectfully requested that this rejection be withdrawn.

V. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record.

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Jane Massey Licata
Registration No. 32,257

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515